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Appendix 7

In re Merck & Co., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986).

54 (Fed. Cir.), *cert. denied*, 105 S.
'84)). The *Erie Resistor* court
ıe issue of patent misuse "goes to
of the right to recover, and not to
of the amount of recovery." *Erie*
) F.2d at 951-52, 132 USPQ at

rences should have been sufficient
ring on notice that patent misuse
ised prior to the trial on validity
ment. Goehring has not claimed
ttempted to include consideration
misuse issue at trial and that the
prevented it from doing so. Here
ınd our pronouncements on the
ufficiently clear to put Goehring
t patent misuse was an issue to be
ial on validity and infringement.
the law is much clearer here than
Evans, where that court quoted
Douglass Aircraft Co., 404 F.2d
2d Cir. 1968):
y wishing to raise the defense (of
ta) is obliged to plead it at the
ıssible moment. Certainty of suc-
an essential element in determin-
ıer to set forth the affirmative
a pleading. If the defense lurks in
vacillation can cause the other
ɔarable injury.
F.2d at 47.

also claims justification for its
t the amended pleading was rel-
ending Lanham Act counterclaim,
antitrust counterclaim might be
Both of these may be justification
g the pleadings, but neither sup-
ıtion for the late date at which the
was offered. Nothing in these two
explains why the amendment
ve been timely made before trial.
e reason, I reject Goehring's at-
ify its late filing by reasoning that
ɔlicy against misuse of patents will
harmed. This was as true before
he trial as it was after.
ıasons discussed above, I am con-
t the time the motion for leave to
iled, Senza-Gel would necessarily
rejudiced by the granting of the
that Goehring failed to show at
l on appeal any compelling reason
amendment to assert new issues
r the jury trial on validity and
. Accordingly, I would reverse the
t motion because the issues were
r the circumstances described in
ıd the district court abused its
'hen it granted the motion to
s would preclude Goehring from
ssues of patent misuse and anti-
ns in the trial of this case, and my

disposition would render moot Goehring's appeal from the denial of summary judgment on the antitrust issue. I would also vacate the district court's summary judgment on patent misuse which arose from the improvident grant of the motion to amend. I would accordingly direct that the proceedings be taken up again from the state they were in prior to the granting of the motion for leave to amend on December 5, 1984. I do not reach the res judicata issue nor issues certified to us, as my disposition would render them moot in this case.

Court of Appeals, Federal Circuit

In re Merck & Co., Inc.

No. 85-2740

Decided September 8, 1986

PATENTS

1. Patentability — Invention — Specific cases — Chemical (§51.5093)

Board of Patent Appeals and Interferences' decision sustaining rejection for obviousness of reexamination claims for antidepressant drug amitriptyline was proper, since claimed drug is structurally similar to other prior art psychotropic compound, imipramine, which is known to possess antidepressive properties, and thus one skilled in medicinal chemical arts would have expected amitriptyline to resemble imipramine in alleviation of depression in humans.

Appeal from Patent and Trademark Office Board of Patent Appeals and Interferences.

Reexamination request, Control No. 90/000264, to reexamine patent of Edward L. Englehardt, Patent No. 3,428,735, issued February 18, 1969, on application, Serial No. 662,907, filed August 24, 1967, as continuation-in-part of application Serial No. 855,981, filed November 30, 1959. From decision sustaining decision rejecting claims 1-3 in reexamination application, applicant appeals. Affirmed; Baldwin, Circuit Judge, dissenting with opinion.

Charles M. Caruso, Rahway, N.J. (Nels T. Lippert, and Fitzpatrick, Cella, Harper & Scinto, New York, N.Y., on the brief, and Mario A. Monaco, and Michael C. Sudol, Jr., both of Rahway, N.J., of counsel) for appellant.

Richard E. Schafer, Associate Solicitor (Joseph F. Nakamura, Solicitor, and Fred E. McKelvey, Deputy Solicitor, on the brief) for Patent and Trademark Office.

Donald R. Dunner, and Finnegan, Henderson, Farabow, Garrett & Dunner, both of Washington, D.C. (Robert D. Bajefsky, Carol P. Einaudi, and Finnegan, Henderson, Farabow, Garrett & Dunner, all of Washington, D.C., on the brief, and Beryl L. Snyder, Elmwood Park, N.J., of counsel) for intervenor Biocraft Laboratories, Inc.

Before Davis, Baldwin, and Archer, Circuit Judges.

Davis, Circuit Judge.

This is an appeal from a final decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), sustaining the rejection of claims 1 through 3 in the reexamination application[1] of U.S. Patent No. 3,428,735[2] (the '735 patent) as unpatentable under 35 U.S.C. § 103. We affirm.

I. BACKGROUND

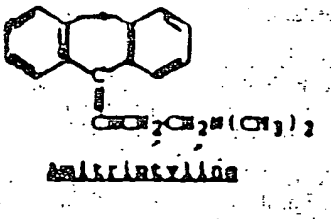
A. *The Invention*

The invention is directed to a method of treating human mental disorders; the method involves treating depression in humans by the oral administration of 5-(3-dimethylaminopropylidene) dibenzo[a,d] [1,4] cycloheptadiene (commonly known as and hereafter referred to as "amitriptyline"), or the hydrochloride or hydrobromide salts thereof,

[1] *Ex Parte Merck and Co.*, Reexamination No. 90/000264, Appeal No. 607-66 (PTO Bd. Pat. App. & Int., May 28, 1985), JA p.7. In its opinion the Board expressly adopted the reasonings in its earlier reissue (for the '735 patent) opinions, *Ex Parte Edward L. Engelhardt*, Reissue Application No. 776,464, Appeal No. 424-40 (PTO Bd. Pat. App., Apr. 23, 1980), JA p. 13 and *Ex Parte Edward L. Engelhardt*, Reissue Application No. 776, 464, Appeal No. 480-01 (PTO Bd. Pat. App., Fed. 25, 1982), JA p. 23.

[2] U.S. Patent No. 3,428,735, issued to Edward L. Engelhardt on February 18, 1969, was based on patent application Serial No. 662,907 filed August 24, 1967 as a continuation-in-part of patent application Serial No. 855,981 filed Nov. 30, 1959.

in a particular dosage range. Amitriptyline has the following chemical structure:



Amitriptyline

As representative of the invention, claim 1 reads:

> 1. A method of treating human mental disorders involving depression which comprises orally administering to a human affected by depression 5-(3-dimethylamino-propylidene) dibenzo [a,d] [1,4] cycloheptadiene or its non-toxic salts in daily dosage of 25 to 250 mg. of said compound.

Remaining claims 2 and 3 are dependent from claim 1 and add limitations pertaining to the use of the hydrochloride and hydrobromide salts of amitriptyline, respectively.

B. *Related Proceedings*

On March 10, 1977 an application, Serial No. 776,464 (the '464 application), was filed for reissue of the '735 patent.[3] All the claims of the '464 application were finally rejected by the examiner under section 102 of title 35, United States Code, and alternatively under section 103 of that title. Subsequently, an appeal (Appeal No. 424–40) was taken to the Board[4] which affirmed the examiner's rejections. Additionally, the Board entered a new rejection under 35 U.S.C. § 103 over a combination of references not previously cited by the examiner. In accordance with 37 C.F.R. § 1.196(b) (1985)[5], appellant elected reconsideration of the '464 application by the examiner. The examiner maintained the rejection entered by the Board; in Appeal No. 480–01, the Board affirmed the examiner. The Board's decision was appealed to the Court of Customs and Patent Appeals (CCPA). Upon the motion of the Commissioner of Patents and Trademarks and on the authority of *In re Dien*, 680 F.2d 151, 214 USPQ 10 (CCPA 1982), the appeal was dismissed for lack of subject matter jurisdiction.[6]

The reissue application was protested by Biocraft Laboratories, Inc. (Biocraft), intervenor in the current appeal. Biocraft is also the plaintiff in a related litigation pending in the U.S. District Court for the District of New Jersey in which the validity and infringement of the '735 patent is in issue. *See Biocraft Laboratories Inc. v. Merck & Co.*, Civil Action No. 77–0693 (D.N.J.). The district court has stayed further action in that case pending the final outcome of the pending PTO proceedings.

C. *Reexamination Proceeding*

Following dismissal of the reissue appeal by the CCPA, Merck & Co., Inc. (Merck), the assignee of the '735 patent, filed for and was granted a request for reexamination of the patent. As a result of prosecution before the examiner, claims 1 through 3 of the reexamination application were finally rejected under 35 U.S.C. § 102 as anticipated by prior art references; the claims were also rejected under 35 U.S.C. § 103 as being obvious over references cited by the Board in its new ground of rejection entered during the initial reissue appeal. Finding the '735 patent to be entitled to the benefit of the November 30, 1959 filing date of its parent application, Serial No. 855,981, the Board reversed the section 102 rejection because the effective filing date of the application antedated all the references cited therein. The Board, however, sustained the rejection for obviousness under section 103. Expressly adopting the reasonings of its earlier reissue opinions, the Board took the position that in view of the prior art, in combination, and a thorough knowledge of the investigative techniques used in the medicinal chemical art, the skilled artisan would have expected the known tricyclic compound, amitriptyline, to be useful as an antidepressant.

D. *The References*

The references relied upon by the Board were:

(1) Rey-Bellet et all (Rey-Bellet) U.S. Patent No. 3,384,663, May 21, 1968 (application filed Mar. 27, 1959);

(2) Kuhn, *Schweizerische Medizinische Wochenschrift*, Vol. 87, No. 35–36, pp. 1135–1140 (Aug. 1957)

[3] The reissue application was filed as a "no defect" type reissue under the then existing 37 C.F.R. § 1.175(a)(4) (1980). That provision has now been repealed.

[4] At that time, the Board of Patent Appeals and Interferences was called the Board of Patent Appeals.

[5] 37 C.F.R. § 1.196(b) provides that when the Board of Appeals determines a new ground of rejection, the appellant may

(1) after submitting appropriate amendments or showing of facts, have the matter reconsidered by the examiner;

(2) waive reconsideration before the examiner and have the case reconsidered by the Board; or

(3) treat the decision, including the new ground of rejection, as a final decision in the case.

[6] *See In the Matter of the Application of Edward L. Engelhardt*, Appeal No. 82–611 (CAFC Oct. 28, 1982) (order granting motion to dismiss).

:d to the Court of Customs
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iissioner of Patents and
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, 214 USPQ 10 (CCPA
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liction.[6]

ication was protested by
es, Inc. (Biocraft), inter-
appeal. Biocraft is also the
litigation pending in the
for the District of New
validity and infringement
is in issue. *See Biocraft*
Merck & Co., Civil Action
J.). The district court has
ı in that case pending the
the pending PTO

roceeding
al of the reissue appeal by
& Co., Inc. (Merck), the
patent, filed for and was
or reexamination of the
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hrough 3 of the reexami-
ere finally rejected under
anticipated by prior art
; were also rejected under
being obvious over refer-
ard in its new ground of
ing the initial reissue ap-
5 patent to be entitled to
ovember 30, 1959 filing
application, Serial No.
reversed the section 102
effective filing date of the
l all the references cited
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ness under section 103
ıe reasonings of its earlier
Board took the position
rior art, in combination
ledge of the investigative
e medicinal chemical art,
ould have expected the
ound, amitriptyline, to be
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ll (Rey-Bellet) U.S. Pat.
May 21, 1968 (applica-
1959);
izerische Medizinische
l. 87, No. 35-36, pp.
957)

the Application of Edward
Jo. 82-611 (CAFC Oct. 28,
otion to dismiss).

(3) Lehman et al. (Lehman), *Canadian Psychiatric Association Journal*, "The Treatment of Depressive Conditions with Imipramine (G 22355)", vol. 3, No. 4, pp. 155-164 (Oct. 1958);

(4) Friedman, *First Symposium On Chemical Biological Correlation*, "Influence of Isosteric Replacements Upon Biological Activity", pp. 296-358 (May 1950);

(5) Burger, *Journal of Chemical Education*, "Rational Approaches to Drug Structure", Vol. 33, No. 8, pp. 362-372 (Aug. 1956);

(6) Petersen et al. (Petersen), *Arzneimittel-Forschung*, Vol. 8, No. 7, pp. 395-397 (1958);

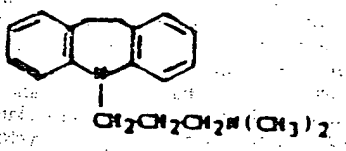
(7) Roche Research Report No. 43,162, pp. 1-9 (Nov. 1957);

(8) Roche Research Report No. 43,169, pp. 1-8 (Apr. 1958);

(9) Roche Research Report No. 52,195, pp. 1-13 (Sept. 1958) (Collectively called the "Roche Reports").

The Rey-Bellet patent disclosed amitriptyline and its hydrochloride salt. Properties of amitriptyline taught by the reference included a "manifold activity upon the central nervous system," as well as pharmacological and medicinal properties, such as "narcosis-potentiating, adrenolytic, sedative, antihistaminic, antiemetic, antipyretic and hypothermic." Rey-Bellet did not disclose or otherwise teach that amitriptyline possessed antidepressive properties.

The Kuhn publication disclosed the compound, imipramine, and taught that the compound was a very effective antidepressant in humans. Imipramine has the chemical structure



Imipramine

and differs from the structure of amitriptyline only in the replacement of the unsaturated carbon atom in the center ring with a nitrogen atom. Kuhn taught a recommended dosage of 75-150 mg per day — possibly 200-250 mg if the smaller doses proved ineffective.

The Lehman publication disclosed the results of a Canadian study of the effects of imipramine on the symptons of depression in humans. This article confirmed, for the most part, the teachings of the Kuhn article.

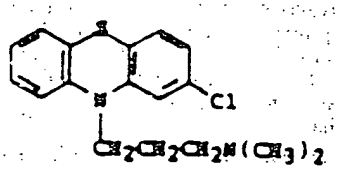
The object of the Freidman publication was "to survey the history of isosterism, to classify the varieties of isosteric replacements which are recorded in the literature, and to note the influence of these replacements on the biological activity of compounds." Friedman defined isosteres as atoms, ions or molecules in which the peripheral layers of electrons can be considered identical. Compounds which fit this broad definition and exhibit the same biological activity were termed "bioisosteric." Further, with respect to the medicinal chemists' use of the theory of "isosteric replacement" or "bio-isosteric replacement" as a tool to predict the properties of compounds, Friedman commented that:

> [t]o the synthetic organic chemist interested in medicinal chemistry, every physiologically active compound of known structure is a challenge - a challenge either to better it, or perhaps merely to equal it. . . .
>
> There are numerous ways of attacking such a problem. . . . One of the methods which has been used frequently, very often with success, is that of isosteric replacement. The examples of this type of replacement in the literature are very numerous, and the fruitful results in the fields of sulfonamides, antimetabolites, and antihistamines are well known.

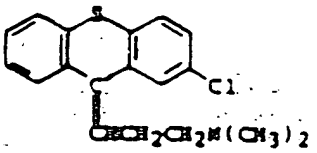
Friedman at page 296. Finally, Friedman disclosed various atoms or groups of atoms as bioisosteric, including the interchange of oxygen and the unsaturated carbon atom which often resulted in similar biological activity. Friedman, however, did not disclose or otherwise teach as bioisoteric the interchange of the nitrogen and unsaturated carbon atoms.

The Burger publication also discussed the theory of "bioisosterism" and its usefulness in designing new drugs based upon the knowledge of "lead" compounds.

The Petersen publication taught, *inter alia*, the properties of chlorpromazine (a phenothiazine derivative) and chlorprothixene (a 9-amino-alkylene-thioxanthene derivative); these compounds have the following structural formulas:



Chlorpromazine



Chlorprothixene

Petersen concluded that, when the nitrogen atom located in the central ring of the phenothiazine compound is interchanged with an unsaturated carbon atom as in the corresponding 9-amino-alkylene-thioxanthene compound, the pharmocological properties of the thioxanthene derivatives resemble very strongly the properties of the corresponding phenothiazines. Using the theory of isosteric replacement, Petersen predicted this similarity in properties:

> Structural chemical considerations permitted the expectation that the 9-aminoalkylene-thioxanthenes . . . would show great similarity to the corresponding phenothiazines. They should be more similar in their behavior to that of the phenothiazines than the saturated 9-aminoalkyl-thioxanthenes. From the physical point of view the π-electron distributions (sites of π - electrons) are almost the same in the phenothiazine derivatives and in the 9-aminoalkylene-thioxanthenes with their stabilizing conjugated double linkage between C9 in the thioxanthene ring and the first C-atom of the side chain...

Petersen at page 3. The compounds were disclosed as having a strong central depressive, i.e., tranquillizing, action in animals.

The Roche Reports revealed the results from tests comparing the pharmacological properties of amitriptyline and imipramine. The reports indicated that the two compounds were very similar in a variety of properties, including their action as tranquilizers having narcosis-potentiating effects. Because of this similarity and because amitriptyline and imipramine were structurally related, Roche scientists concluded that amitriptyline should be clinically tested for depression alleviation — a known property of imipramine. In the pharmalogical guideline for the clinical testings of amitriptyline (which was labelled Roche Preparation Ro 4-1575), the Roche Reports stated that

> [i]t is to be noted that a "tofranil-like effect" is already to be expected by using a dose ¼ — ½ that of Tofranil. Side effects which can appear . . . are sedative and atropine-like effects, such as appear also with Tofranil.[1]

We must decide in this appeal whether appellant's invention would have been prima facie obvious over the available prior art of record; and, if so obvious, whether the prima facie case has been rebutted by evidence of unexpected results.

III. DISCUSSION

In its opinion on this problem, the Board expressly followed the guidelines of *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 466-67 (1966), and made findings on factual inquiries specifically set forth in that decision. These factual findings must be accepted unless they are clearly erroneous. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), *cert. denied*, 105 S.Ct. 1173 (1985); *In re De Blauwe*, 736 F.2d 699, 703, 222 USPQ 191, 193 (Fed. Cir. 1984); *accord Stock Pot Restaurant, Inc. v. Stockpot, Inc.*, 737 F.2d 1576, 1578-79, 222 USPQ 665, 666-67 (Fed. Cir. 1984). In this case we do not hold the Board's factual findings — as to the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art — to be clearly erroneous and accordingly we have followed them in our statement of the prior art and we now follow them in our analysis of the legal issue of obviousness.

Prima Facie Obviousness: The prior art taught that amitriptyline and imipramine are both psychotropic drugs which react on the central nervous system and which were known in the art prior to the time of appellant's invention. Imipramine was known to possess antidepressive properties in humans. While amitriptyline was known to possess psychotropic properties such as sedative and narcosis-potentiating properties, the drug was not known to be an antidepressant. However, the prior art has shown that imipramine and amitriptyline are unquestionably closely related in structure. Both compounds are tricyclic dibenzo compounds and differ structurally only in that the nitrogen atom located in the central ring of imipramine is interchanged with an unsaturated carbon atom in the central ring of amitriptyline. To show obviousness, it was necessary to determine from knowledge already available in the art at the time of appellant's invention that one skilled in the medicinal chemical art would have expected amitriptyline, like imipramine, to be useful in the treatment of depression in humans. *In re*

[1] Tofranil is a tradename used for imipramine.

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. DISCUSSION

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83 U.S. 1, 17-18, 148 USPQ
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1516, 1520, 222 USPQ 369,
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191, 193 (Fed. Cir. 1984);
Restaurant, Inc. v. Stockpot,
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Obviousness: The prior art
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Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

As found by the Board, the Roche Reports recognized the structural relationship between amitriptyline and imipramine and concluded that amitriptyline should be tested for its antidepressant activities. In fact the Roche Reports expressly stated that amitriptyline was expected to resemble imipramine clinically in its depression alleviation effects.

"Structural similarity, alone, may be sufficient to give rise to an expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). However, the Board did not rest its conclusion of obviousness on structural similarity alone. Rather, the Board further recognized that in attempting to predict the biological activities of a drug, a skilled medicinal chemist would not proceed randomly, but would base his attempts on the available knowledge of prior research techniques, and literature used in his field. The prior art showed that one such technique was "bioisosteric replacement" or the theory of bioisosterism — where the substitution of one atom or group of atoms for another atom or group of atoms having similar size, shape and electron density provides molecules having the same type of biological activity. Finding that the Friedman, Burger and Petersen references taught that bioisosterism was commonly used by medicinal chemists prior to 1959 in an effort to design and predict drug activity, the Board concluded that one of ordinary skill in the arts would have been aware of this technique at the time of appellant's invention.[8] Further, the Board found that Petersen taught as bioisosteric the interchange of the nitrogen and unsaturated carbon atoms — the precise structural difference between imipramine and amitriptyline.[9]

We see no clear error in the Board's determination as to the teachings of the prior art references, in combination. In view of these teachings, which show a close structural similarity and a similar use (psychotropic drugs) between amitriptyline and imipramine, one of ordinary skill in the medicinal chemical arts, possessed of the knowledge of the investigative techniques used in the field of drug design and pharmacological predictability, would have expected amitriptyline to resemble imipramine in the alleviation of depression in humans. Accordingly, we agree with the Board that appellant's invention was prima facie obvious over the prior art of record.

In traversing the Board's decision of obviousness, appellant has urged that the Board's decision was premised on an impermissible "obvious to try" standard. Appellant contends that there was no motivation in the prior art to arrive at appellant's invention. "[O]bvious to try is not the standard of 35 U.S.C. § 103." *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977) (emphasis omitted). Rather, the test is whether the references, taken as a whole, would have suggested appellant's invention to one of ordinary skill in the medicinal chemical arts at the time the invention was made. *In re Simon*, 461 F.2d 1387, 1390, 174 USPQ 114, 116 (CCPA 1972). Clearly, amitriptyline and imipramine, both known psychotropic drugs, are closely structurally related. The expectation that the similar structures would behave similarly was suggested in the Roche Reports. In combination with those teachings, the prior art teaching that the precise structural difference between amitriptyline and imipramine involves a known bioisosteric replacement provides sufficient basis for the required expectation of success, without resort to hindsight.[10] Obviousness does not require absolute predictability. *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976). Only a reasonable expectation that the beneficial result will be achieved is necessary to show obviousness. *In re Longi*,

[7] Appellant submitted the declaration of Dr. Paul N. Craig, an experienced medicinal chemist, JA p. 372. His view was that the concept of bioisosterism could not be used in 1959 to predict the antidepressant effects in amitriptyline or the pharmacological differences between imipramine and amitriptyline. Dr. Craig stated:

> [I]n my opinion "isosterism" in 1959 afforded no basis for predicting the specific pharmaceutical utility in humans, and it is my belief that that is still true today . . . . I do not believe the carryover of tranquilizing activity from chlorpromazine to chlorprothixene afforded a reasonable basis for predicting the carryover of antidepressant properties from imipramine to amitriptyline.

Affidavit of Paul N. Craig, JA, pp. 374-75.

[8] Plainly the Board was not clearly erroneous in discounting that testimony. There was independent evidence in the record to the contrary. The Friedman, Burger and Petersen references recognize that concept as a means of predicting biological properties in isosterically-related compounds prior to 1959.

[9] Petersen even went so far as to suggest that the apparent bioisosteric relationship between the interchange of the nitrogen and unsaturated carbon atoms led to the design of chloroprothixene in the expectation that the compound would share the same biological activity as chlorpromazine. *See* Petersen, *supra*, at p. 395.

[10] The teachings of the Roche Reports as well as the Petersen reference distinguish this case from *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("there is no motive in the cited art to make the modification required to arrive at appellants' compounds").

759 F.2d 887, 897, 225 USPQ 645, 651 (Fed. Cir. 1985).

We also find untenable appellant's arguments that Petersen teaches away from appellant's invention. Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Thus, Petersen must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole. That teaching is that the interchange of the nitrogen and the unsaturated carbon atoms is isosteric and compounds so modified are expected to possess similar biological properties.

Neither are we persuaded by appellant's contention that the Board erred in relying on the contemporaneous independent invention of others to support its holding of obviousness.[11] As we have said earlier, the teachings of the prior art references in combination adequately support the Board's conclusion. However, the additional, although unnecessary, evidence of contemporaneous invention is probative of "the level of knowledge in the art at the time the invention was made." *In re Farrenkopf*, 713 F.2d 714, 720, 219 USPQ 1, 6 (Fed. Cir. 1983).

Unexpected Results: A prima facie case of obviousness can be rebutted by evidence of unexpected results. *In re Davis*, 475 F.2d 667, 670, 177 USPQ 381, 384 (CCPA 1973). In rebuttal of the PTO's prima facie case appellant has asserted that, as compared to imipramine, amitriptyline unexpectedly has a more potent sedative and a stronger anticholinergic effect. In support of this contention, appellant has relied on an affidavit of Dr. Joseph J. Schildkraut,[12] a psychiatrist and a Professor of Psychiatry at Harvard, and also on a published record of a symposium of physicians and psychiatrists concerned with the treatment of the depressed patient.[13]

Dr. Schildkraut's affidavit recognizes some pharmacological differences between amitriptyline and imipramine including the fact that amitriptylne is a more potent sedative and has a strong anticholinergic effect than imipramine. Further, Dr. Schildkraut notes that depressed patients have responded differently to amitriptyline and imipramine, some responding to one and not the other or more favorably to one than to the other. For the most part, the record of the cited symposium confirms the differences noted in the Schildkraut affidavit.[14] That record also counseled practicing physicians on choosing from the spectrum of tricyclic antidepressants (a term which includes amitriptyline and imipramine) the particular drug useful for an individual patient.

After a careful consideration of all the evidence, we are persuaded that the Board did not err in determining that the alleged unexpected properties of amitriptyline are not so unexpectedly different from the properties of imipramine, the closest prior art, as to overcome the prima facie showing of obviousness. The prior art of record clearly taught that amitriptyline was a known sedative.[15] The evidence before us (which was, of course, before the Board) further revealed that all tricyclic antidepressant drugs, in general, possess the secondary properties of sedative and anticholinergic effects. Specifically, the record showed that during the prosecution of the reissue application, appellant submitted an article entitled "Using the tricyclic antidepressants" which included a table comparing the properties of known tricyclic antidepressant drugs.[16] Included in these properties were sedative and anticholinergic effects of the known antidepressants.[17] Thus, it appears that the alleged difference in properties between amitriptyline and imipramine is a matter of degree rather than kind. Moreover, as to the sedative effects, the article revealed only a slight difference between the two compounds. Amitriptyline was characterized as "highly sedative" while imipramine was only "somewhat less [sedative] than amitriptyline."[18] Regarding

[11] *Ex Parte Edward L. Engelhardt*, Appeal No. 424-40, *supra* note 1, at pp. 23-24, JA pp. 22(l)-22(m), where the Board indicated that evidence before it revealed that four other groups of inventors independently and contemporaneously discovered amitriptyline's antidepressant properties using reasoning based on a thorough knowledge of investigative techniques, which included the concept of isosterism, used in the medicinal art area.

[12] Affidavit of Joseph J. Schildkraut; JA p. 366.

[13] Symposium, *Depression Today — Experts Answer Your Questions*, JA p. 309.

[14] Dr. Schildkraut was a member of the symposium.

[15] Rey-Bellet, *supra*, col. 2, line 16.

[16] *Patient Care*, "Using the Tricyclic Antidepressants," pp. 28-33, 39-40, 43-45, 49-52, 57-58, 63-64, 67-68, 71, 75-76, 78, 81 84-85, (May 15, 1979); *see also* Commission's Appendix, pp. CA 17-45.

[17] *See also* the Symposium, *Depression Today — Experts Answer Your Questions*, *supra*, note 13, at p. 315, where Dr. Hollister indicates that when choosing from the spectrum of tricyclic antidepressant drugs, the choice is based on three pharmocological actions including (1) the amount of sedation (2) the amount of anticholinergic effect and (3) the nature of the drugs in primarily blocking the uptake of serotin or norepinephrine.

[18] *Patient Care*, "Using The Tricyclic Antidepressants," *supra* note 16, at p. 50.

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a, col. 2, line 16.

Using the Tricyclic Antidepres-
39–40, 43–45, 49–52, 57–58,
5–76, 78, 81 84–85, (May 15,
mission's Appendix, pp. CA

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ephrine.

"Using The Tricyclic Anti-
ote 16, at p. 50.

the anticholinergic effect, the article showed that both drugs have anticholinergic effects but to a different degree. These are not truly unexpected results. The Board found in one of its reissue opinions (incorporated in the reexamination decision now on appeal): "[i]n regard to the sedative and anticholinergic properties of amitriptyline, we are not convinced that the side effects of this material [amitriptyline] are significantly or unexpectedly different from the level of those properties exerted by the closest prior art antidepressant, imipramine."[19]

The core of it is that, while there are some differences in degree between the properties of amitriptyline and imipramine, the compounds expectedly have the same type of biological activity. In the absence of evidence to show that the properties of the compounds differed in such an appreciable degree that the difference was really unexpected, we do not think that the Board erred in its determination that appellant's evidence was insufficient to rebut the prima facie case. The fact that amitriptyline and imipramine, respectively, helped some patients and not others does not appear significant. As noted by the Board, a difference in structure, although slight, would have been expected to produce some difference in activity.

[1] In sum, we hold that the claimed invention would have been obvious to one of ordinary skill in the art. Accordingly, the decision of the Board is

AFFIRMED.

Baldwin, Circuit Judge, dissenting.

The rejection by the board is flawed because it did not analyze the invention according to the requirement of 35 U.S.C. § 103. The board wrote:

> The issue before us in considering the instant claims on their merits for patentability is whether the artisan having the requisite skill in the pertinent art area and a knowledge of the available prior art would have been motivated to employ amitriptyline in the treatment of human depression.

That is, whether it would have been obvious to try amitriptyline as an antidepressant. Guided by the disclosure of the applicant, the board pieced together information from various patents, journal articles, and papers, and concluded:

> It remains our position that one having ordinary skill in this art are [sic] would have been familiar with the concept of bioisosterism and because of this knowledge would have concluded that the known compound, i.e., amitriptyline, would be *potentially* useful as an antidepressant. [Emphasis ours.]

That is, it would have been obvious to try amitriptyline as an antidepressant. Obvious-to-try is not the test for patentability under 35 U.S.C. § 103. This court and its predecessor, the CCPA, have repeatedly rejected that approach. *In re Godwin,* 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978); *In re Antoine,* 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); *In re Lindell,* 385 F.2d 453, 455, 155 USPQ 521, 523 (CCPA 1967); *In re Tomlinson,* 363 F.2d 928, 150 USPQ 623 (CCPA 1966); *In re Papesch,* 315 F.2d 381, 137 USPQ 43 (CCPA 1963); *see also In re Grabiak,* 769 F.2d 729, 226 USPQ 870 (Fed. Cir. 1985).

Congress has also rejected that approach by enacting the second sentence of 35 U.S.C. §103, which states "[p]atentability shall not be negatived by the manner in which the invention was made." The reviser's note on this sentence states "it is immaterial whether it resulted from long toil and experimentation or from a flash of genius."

The obvious-to-try analysis is an attack on the method of making an invention that specifically penalizes people in areas of endeavor where advances are won only by great effort and expense. The pharmaceutical field is particularly hard hit because there is an over abundance of structures that are obvious to try. Consider, for example, the Peterson reference which the majority cites to demonstrate the possibility that a nitrogen atom may be replaced by a double-bonded carbon atom. This journal article records an attempt to find drugs useful for the treatment of endogenous psychoses, i.e., tranquilizers. The researchers tested eighteen chemicals with closely related structures. These materials were injected into mice, and compared for their ability to make the mice fall asleep. The results of these may be tantalizing and useful, but only as a guide for further research. I agree that, based on this information and the other references cited by the board, the researcher with ordinary skill in the art would be motivated to investigate the possibility of substituting a double-bonded carbon atom for nitrogen. The researcher would also be motivated to test every other structural variation in Peterson, as well as a host of others. Under an obvious-to-try analysis, any of these structures which ultimately is shown to be effective as an antidepressant in human beings would be unpatentable because the researcher dared to follow a logical plan.

[19] *Ex Parte Edward L. Engelhardt,* Appeal No. 480-01, supra note 1, at p.12 JA p. 34

The board and the majority also err by reading too much certainty into the teachings of the references. They have not considered the references as a whole. Friedman discusses the phenomenon that compounds with similar chemical structures sometimes behave in a similar fashion in a biological system. Once such a compound has been tested and found to have the same biological activity, it is called "bio-isosteric."[1]

Friedman also teaches that an isosteric compound "may have the same activity as the original, *or more usually* it may have an *antagonistic* effect." (Emphasis added.) Friedman explains that in order to predict biological activity with accuracy, one ideally should know (1) the mechanism by which the original drug acts and (2) what part of the structure of the original drug is critical to the original drug activity.[2] That reference also unequivocally states that comparisons should be made in living systems, but such information is not easily available. That reference relies on *in vitro* testing, and it specifically states that *in vitro* results may or may not correlate with clinical studies. It also clearly states that, for the purposes of its discussion, biological activities such as absorption, distribution, conjugation (detoxification), taste, odor and *side effects of drugs* will be ignored. Friedman concludes that compounds with similar structures need not be bio-isosteric.

The Burger reference does discuss bio-isosterism and its usefulness in designing new drugs. Its evaluation of bio-isosterism as a tool for predicting drug activity is as follows:

> However, if one can achieve a gradual change of biological behavior and follow it accurately at each step of minor structural alteration, one is bound to enhance one property, suppress another, and ultimately arrive at a drug suitable for therapy. Shortcuts to this disconcertingly tedious process have not been found, and this is probably responsible for the still prevailing opinion that new useful drugs will be discovered most easily by more or less empirical procedures.

at page 369, and

> Slight sterochemical or structural changes may alter considerably the biological role of a compound. Patient variation of at least a reasonable number of structures is still the only answer to this question.

at page 370.

The Roche reports contain background information about various pharmacological effects of amitriptyline. The information was derived from testing for its toxicity and tranquilizing effect on animals. This information would be essential to a decision to clinically test the drug. It is not sufficient to show the drug would be useful for treating human beings. Congress gave pragmatic recognition to the difficulty of determining whether a new drug is useful by its enactment of the 1962 amendment to 21 U.S.C. § 321. That action was taken in response to problems caused by another tranquilizer, thalidomide.

Neither these references, nor the other references cited by the board and the majority purport to teach the worker with ordinary skill in the art that amitriptyline is a drug that is useful for treating depression in human beings. That conclusion is steps removed from the information presented by these sources. I would reverse.

[1] The term "bio-isosteric" therefore is simply a conclusion drawn after testing. The label is properly limited to the system and purpose for which the compounds were tested. For example, two drugs could be bio-isosteric with respect to making mice fall asleep, and not bio-isosteric when tested at a particular dosage level for the treatment of high blood pressure in human beings. The theory of bio-isosterism as used by the board and majority is nothing more or less than an analysis of structural obviousness.

[2] Neither this reference nor any of the others purport to disclose either piece of information.

Court of Appeals, Federal Circuit

George v. Honda Motor Co., Ltd., et al.

No. 85-2612

Decided September 30, 1986

PATENTS

1. Infringement — Substitution of equivalents — In general (§39.751)

Federal district court did not err in granting summary judgment that accused engines do not infringe either literally or under doctrine of equivalents, based upon finding that claimed air-cooled cylinder head structure, unlike accused cylinder which is cooled at least in part by water, does not encompass water-jacket head structure either literally or under doctrine of equivalents.

Particular patents — Engine Cylinders

4,108,118, George, Water Jacket Cylinder, holding of non-infringement affirmed.

ıresent Order revises the reference to
:ctive date of copyright restoration
ıe Uruguay Round Agreements Act
.) in the Court's August 19, 1996
40 USPQ2d 1506] granting plain-
lotion for Partial Summary Judg-
n the August 19, 1996 Order, the
eferred to Presidential Proclamation
53 of December 23, 1994 (60 Fed.
)03 (Jan. 4, 1995)) to conclude that
: of restoration for URAA works was
/ 1, 1995. *See* Order at pages 13, 16.
. later Presidential document, Procla-
No. 6780 of March 23, 1995 (60 Fed.
3845 (March 27, 1995)) clarifies that
ons of the Uruguay Round Agree-
n Trade-Related Aspects of Intellec-
operty Rights (TRIPs) relating to
ht restoration did not take effect until
y 1, 1996. Proclamation No. 6780
n pertinent part at Section 5:
ırticle 65, paragraph 1, of the TRIPs
:ement provides that no WTO mem-
hall be obliged to apply to provisions
is Agreement until one year after the
of entry into force of the WTO
:ement with respect to the United
:s was January 1, 1995.
The statement of administrative ac-
approved by the Congress in section
a)(2) of the URAA (19 U.S.C.
(a)(2)) provides that, "in general,
right will be restored on the date
ı TRIPs Agreement's obligations take
:t for the United States."
Accordingly, I have decided that it is
ssary and appropriate, in order to im-
ıent the TRIPs Agreement and to en-
that section 514 of the URAA is
opriately implemented, to proclaim
the date on which the obligations of
TRIPs Agreement will take effect for
United States is January 1, 1996.
mation No. 6780 of March 23, 1995
d. Reg. 15845 (March 27, 1995)).
Court emphasizes that the present
ation does not affect the Court's Au-
), 1996 ruling.

IS SO ORDERED.

U.S. Court of Appeals Federal Circuit

United States Surgical Corp. v. Ethicon Inc.

Nos. 94-1386, -1419

Decided January 3, 1997

PATENTS

1. Patentability/Validity — Obviousness — In general (§115.0901)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Jury trials (§410.42)

Federal district court properly instructed jury on issue of obviousness in patent infringement action, since jury was correctly instructed on presumption of validity and that defendant bore burden of proving invalidity by clear and convincing evidence, and that it was necessary to consider scope and content of prior art, differences between prior art and claimed invention, level of ordinary skill in art, and objective criteria of nonobviousness, since instructions included explanation of principles to be applied in determining obviousness when invention is combination of prior art components, and since instructions were correct in law, thorough, and clearly stated.

PATENTS

2. Patentability/Validity — Obviousness — In general (§115.0901)

Patent construction — Claims — In general (§125.1301)

Federal district court need not repeat or restate every claim term in order to comply with rule that claim construction is for court rather than jury, since claim construction is matter of resolution of disputed meanings and technical scope, to clarify and if necessary explain what patentee covered by claims, for use in determination of infringement, rather than obligatory exercise in redundancy; although claim construction may occasionally be necessary in obviousness determinations, when meaning or scope of technical terms and words of art is unclear and requires resolution in order to determine obviousness, in present case none of rejected jury instructions concerning claim construction was directed to, or has been reasonably shown to affect, determination of obviousness.

PATENTS

3. Patentability/Validity — Obviousness — In general (§115.0901)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Jury trials (§410.42)

Federal district court did not commit prejudicial error by providing dictionary to jury during its deliberations in patent infringement trial in which asserted claims were held invalid for obviousness, since district court explained in post trial opinion that jury instruction to consider ordinary meaning of claim language, and general assumption that definitions of dictionary are common knowledge with which jury is charged, support provision of dictionary, since provision of dictionary to jury, although not favored, is not grounds for new trial, and since plaintiff has offered no specifics as to words whose dictionary definitions may have adversely affected verdict of obviousness, and no suggestion that jury disregarded court's instructions on law of obviousness or plain meaning of terms used in claims and prior art.

PATENTS

4. Patentability/Validity — Obviousness — In general (§115.0901)

Patent construction — Claims — In general (§125.1301)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Jury trials (§410.42)

Federal district court's rejection of proposed jury instructions directed to construction of patent claims did not prejudice jury's determination of obviousness, since district court is not required to parse claims for jury in every case, whether or not there is issue in material dispute as to meaning or scope of claims, since infringement plaintiff has not shown that there are unclear or ambiguous technical terms or words of art or related aspects of claim scope whose "construction" would negate verdict of obviousness, and has not explained how any reasonable claim construction it requested would have deprived obviousness verdict of its support, and since trial court is not authorized to remove from jury factual findings underlying obviousness determination.

Particular patents — General and mechanical — Surgical clip application

5,084,057, Green, Bolanos, Young, McGarry, Heaton, and Ratcliff, apparatus

and method for applying surgical clips in laparoscopic or endoscopic procedures, judgment that claims 1, 2 and 7 are invalid for obviousness affirmed.

5,100,420, Green, Bolanos, Young, McGarry, Heaton, and Ratcliff, apparatus and method for applying surgical clips in laparoscopic or endoscopic procedures, judgment that claim 1 is invalid for obviousness affirmed.

On remand from the U.S. Supreme Court.

Action by United States Surgical Corp. against Ethicon Inc. and Johnson & Johnson Hospital Services Inc. for patent infringement. The U.S. District Court for the District of Connecticut entered judgment for defendants on jury verdicts that plaintiff's patent no. 5,100,420 is infringed but invalid for obviousness, and that plaintiff's patent no. 5,084,057 is not infringed and invalid for obviousness. On appeal, the U.S. Court of Appeals for the Federal Circuit affirmed without opinion pursuant to Fed.Cir.R. 36. Following grant of certiorari, the U.S. Supreme Court vacated that affirmance and remanded for further consideration in light of its decision in *Markman v. Westview Instruments Inc.* (38 USPQ2d 1461). On remand, district court's judgment is affirmed on ground of invalidity of patents in suit based on obviousness.

William E. McDaniels, J. Alan Galbraith, and David S. Blatt, of Williams & Connolly, Washington, D.C.; Basam E. Nabulsi, Thomas R. Bremer, and John C. Andres, Norwalk, Conn., for plaintiff-appellant.

David F. Dobbins, Gregory L. Diskant, and Eugene M. Gelernter, of Patterson, Belknap, Webb & Tyler, New York, N.Y., for defendants/cross-appellants.

Before Newman, circuit judge, Bennett, senior circuit judge, and Rader, circuit judge.

Newman, J.

The court's prior judgment of this appeal and cross-appeal was vacated by the Supreme Court and remanded "for further consideration in light of *Markman v. Westview Instruments, Inc.*, 517 U.S. ____ (1996)." *U.S. Surgical Corp. v. Ethicon, Inc.*, 116 S. Ct. 1562 (1996). Our prior judgment affirmed the judgment of the United States District Court for the District of Connecticut,[1] entered on jury verdicts that claim 1 of U.S. Surgical's United States Patent No. 5,100,420 (the '420 patent) is infringed but invalid for obviousness, and that claims 1, 2, and 7 of United States Patent No. 5,084,057 (the '057 patent) are not infringed and are invalid for obviousness. The issue of inequitable conduct during patent prosecution was decided before trial, by summary judgment in favor of U.S. Surgical. Each of U.S. Surgical and Ethicon appealed the rulings adverse to it. After full briefing and oral argument this court entered judgment pursuant to Federal Circuit Rule 36:

> Rule 36: Judgment of affirmance without opinion.—
>
> The court may enter a judgment of affirmance without opinion, citing this rule, when it determines that any of the following circumstances exist:
>
> (a) the judgment, decision or order of the trial court appealed from is based on findings that are not clearly erroneous;
>
> (b) the evidence in support of a jury verdict is sufficient;
>
> (c) summary judgment, directed verdict, or judgment on the pleadings is supported by the record;
>
> (d) the decision of an administrative agency warrants affirmance under the standard of review in the statute authorizing the petition for review; or
>
> (e) a judgment or decision has been entered without an error of law;
>
> and an opinion would have no precedential value.

Appeals whose judgments are entered under Rule 36 receive the full consideration of the court, and are no less carefully decided than the cases in which we issue full opinions. The Rule permits the court to dispense with issuing an opinion that would have no precedential value, when the circumstances of the Rule exist. *See Taylor v. McKeithen*, 407 U.S. 191, 194 n.4 (1972) ("We, of course, agree that the courts of appeals should have wide latitude in their decisions of whether or how to write opinions. That is especially true with respect to summary affirmances.")

Seven weeks after this decision, reported at 48 F.3d 1237 (Fed. Cir. 1995) (Table), for which rehearing and rehearing *en banc* were denied, the Federal Circuit decided *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 34 USPQ2d 1321 (Fed. Cir. 1995) (*en banc*). The Supreme Court granted certiorari in *Markman* and also upon U.S. Surgical's petition. After deciding the *Markman* appeal, reported at 517 U.S. , 116 S. Ct. 1384, 38 USPQ2d 1461 (1996), the Court instructed the Federal Circuit to give further consideration to U.S. Surgical's case in light of the

[1] *U.S. Surgical Corp. v. Ethicon, Inc.*, No. 5:92 CV 00134 (AVC), (D. Conn. Feb. 11, 1993 (Summary Judgment); February 18, 1994 (Judgment Order); June 9, 1994 (Ruling on Post-trial Motions)).

Court's decision in *Markman*. We have done so.

The judgment of the district court is affirmed, on the ground of invalidity of the '420 and '057 patents based on obviousness. We do not reach the issues of infringement and the conditional cross-appeal of the issue of inequitable conduct. *See Consolidated Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 814, 15 USPQ2d 1481, 1489 (1990) ("a party may defend a judgment 'on any ground properly raised below' ") (citing *Washington v. Yakima Indian Nation*, 439 U.S. 463, 476 n.20 (1979)); *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1123, 39 USPQ2d 1100, 1107 (Fed. Cir. 1996) ("No further public interest is served by our resolving an infringement question after a determination that the patent is invalid."). We now fully explain our decision.

The U.S. Surgical Inventions

The inventions claimed in the '420 patent and its continuation-in-part the '057 patent are for a surgical instrument for ligating blood vessels and other tissues during endoscopic surgery, by applying multiple ligating clips in sequence.

Endoscopic surgery is a procedure whereby instead of opening the abdomen or other body cavity by incision to provide open access to the surgical site, the surgery is performed by inserting the surgical instruments into the body through small tubes called trocars. The small size of the incisions that accommodate the trocars results in less tissue damage, less pain, and faster healing than for traditional open surgery. In performing endoscopic surgery the body cavity is inflated with a gas, called aninsufflating gas, to provide working space. For most procedures today a miniature video camera is used to televise the surgical site, the enlarged video image appearing upon an external screen and guiding the surgeon or surgical team in manipulating the instruments through the trocars.

Endoscopic surgery was in somewhat limited use for many years, having been used mostly for the ligation of fallopian tubes, the surgeon viewing the site through an eyepiece. Endoscopic procedures experienced rapid expansion after about 1989, particularly for gallbladder removal. Witnesses disputed at trial whether the expansion was due to the development of the miniature video camera or the development of U.S. Surgical's endoscopic multiple clip applier.

During both endoscopic and open surgery, blood vessels may be closed and tissues clamped using small "U" shaped clamps called ligating clips. Ligating clips are applied by an instrument that positions the clip about the tissue or vessel to be secured and then compresses the clip. When initially developed, ligating clip instruments were capable of being loaded with only one clip at a time, and required reloading between each application. Then U.S. Surgical developed a ligating clip applier for open surgical use that applied multiple clips in succession, without reloading the instrument. This instrument, having the brand name "Premium Surgiclip," is the subject of United States Patent No. 5,030,226 (the '226 patent). The Premium Surgiclip and the '226 patent are prior art to the '420 and '057 patents in suit, and were the subject of extensive testimony at trial.

At trial witnesses explained the subsequent development of the instrument of the patents in suit, a ligating clip applier for endoscopic use that applies multiple clips in succession without withdrawing and reloading the instrument. U.S. Surgical's instrument, having the brand name EndoClip, was the first multiple clip applier for endoscopic use. The instrument is depicted in the '420 patent as follows:

FIG. 1

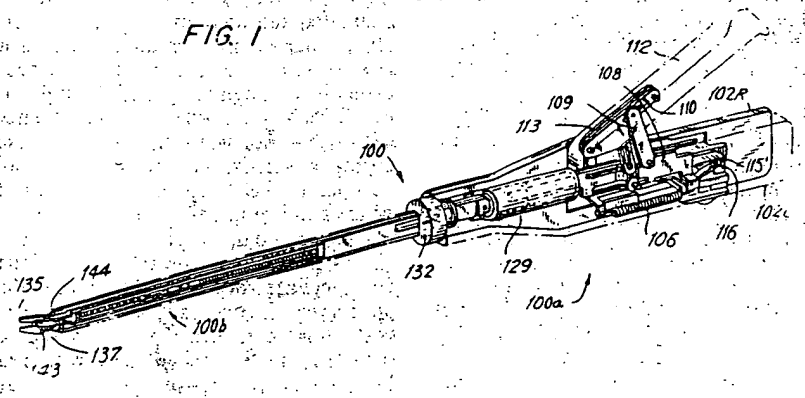

Fig. 1 of '420 patent.

The instrument is depicted in the '057 patent with a different handle, as follows:

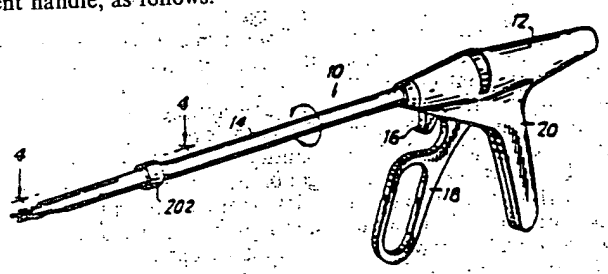

Fig. 1 of '057 patent.

It is seen that these instruments have an elongated shank that holds the ligating clips and is shaped for endoscopic use through a trocar. After insertion into the body cavity a clip is pushed into position in the jaws using controls on the handle, and the clip is applied to the tissue to be ligated by closing the jaws using controls on the handle. The jaws are then opened and the next clip is pushed into position. Thus successive clips may be applied without withdrawing the instrument from within the body.

Claim 1 of the '420 patent is directed to the combination of the trocar and the clip applier, each component having defined limitations. Claim 1 is the only '420 patent claim in suit:

1. In combination:

a) a trocar having a cannula, and valve means for sealing said cannula, said cannula being adapted for entry into a body cavity;

b) an endoscopic clip applier having:

i) a frame;

ii) an endoscopic portion defining a longitudinal axis and extending distally from said frame, said endoscopic portion being insertable into said cannula through said valve means in sealing engagement therewith, said endoscopic portion further including a plurality of surgical clips disposed in an array and clip closing means for sequentially closing said surgical clips; and

iii) seal means associated and adapted to cooperate with at least one of said endoscopic portion and said frame to obstruct passage of gaseous media from the body cavity.

Claim 1, the broadest claim of the '057 patent, also describes the endoscopic apparatus as comprising several elements. The claim elements are defined in terms of their function, as provided in 35 U.S.C. §112 ¶6:

1. An apparatus for endoscopic application of surgical clips to body tissue which comprises:

a) frame means;

b) endoscopic means connected to said frame means of generally elongated configuration and extending distally from said frame means and including:

i) means for storing a plurality of surgical clips;

ii) means for individually advancing said clips to the distal portion of said endoscopic means for positioning adjacent the body tissue to be clipped;

iii) means for at least partially closing said clip at least sufficient to grip the body tissue after the clip has been advanced distally to said distal portion of said endoscopic means; and

iv) gaseous sealing means.

Claim 2 of the '057 patent specifies the use of silicon grease as the gaseous sealing means of clause iv, and claim 7 is directed to a disposable device as in claim 1.

Ethicon's defense that the claims are invalid for obviousness was based on the ground that U.S. Surgical had merely adapted to endoscopic use its own, prior art multiple clip applier, the Premium Surgiclip of the '226 patent, by known and routine adaptation. Thus Ethicon presented evidence and argument that U.S. Surgical had simply elongated the body of its prior art multiple clip applier so that it could be used through a trocar, with a sealing means to prevent escape of the insufflating gas through the trocar. Ethicon adduced extensive evidence that such adaptation was well known to persons of ordinary skill in the field of endoscopic instruments. U.S. Surgical countered with evidence and argument to the contrary.

The jury held, by special verdicts, that the claims in suit were invalid for obviousness. On appellate review we determine whether, on correct instructions of law, there was substantial evidence whereby a reasonable jury could have reached the verdict reached by this jury. *See Litton Sys., Inc. v. Honeywell, Inc.*, 87 F.3d 1559, 1566, 39 USPQ2d

1321, 1324 (Fed. Cir. 1996) ("Substantial evidence describes that minimum quantum of evidence from which a jury might reasonably afford relief."); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 72 F.3d 857, 862, 37 USPQ2d 1161, 1163 (Fed. Cir. 1995) ("Substantial evidence is such relevant evidence, on the record as a whole, as could be accepted by a reasonable mind as adequate to support the verdict.") Conflicting evidence and argument must be viewed as resolved favorably to the party in whose favor the jury found. The reviewing court must give appropriate deference to the jury's choices in weighing the evidence, in deciding between opposing positions, and in drawing factual inferences. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) (" 'the appellate court's function is exhausted when that evidentiary basis [of the jury's verdict] becomes apparent, it being immaterial that the court might draw a contrary inference or feel that another conclusion is more reasonable.' ") (quoting *Lavender v. Kurn*, 327 U.S. 645, 653 (1946)); *Medtronic, Inc. v. Intermedics, Inc.*, 799 F.2d 734, 742, 230 USPQ 641, 646 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1033 (1987).

The Prior Art

As we have remarked, Ethicon's position was that U.S. Surgical had simply elongated its prior art multiple ligating instrument so that it could be inserted through a trocar, and used known endoscopic sealing mechanisms to inhibit escape of the insufflating gas through the trocar. Expert witnesses testified that these modifications were well known to persons of ordinary skill in the art of endoscopic instruments. The witnesses presented several prior art patents, and exhibited many actual instruments, all having the common endoscopic characteristics of an elongated body and sealable engagement with the trocar.

The district court mentioned, in the opinion accompanying the denial of post-trial motions, that U.S. Surgical's technical expert testified that there were approximately forty different prior art multiple clip appliers for conventional open surgery. He testified that at least four of them — the Premium Surgiclip of the '226 patent and the multiple clip appliers shown in the Montgomery patent, the Peters patent, and the Lachakar patent — embodied all of the elements of the '420/'057 claims except for the elongated body and sealing means. He testified that an elongated body and sealing means are characteristics of all endoscopic surgical instruments. In evidence were a variety of actual instruments for endoscopic surgery, all having these characteristics. These endoscopic instruments included graspers, scissors, dissectors, and single clip appliers. All had an elongated body and were adapted for sealing engagement with the trocar.

Also in evidence were references describing prior endoscopic devices for the application of multiple fasteners other than ligating clips. U.S. Patent No. 3,870,048 to Yoon showed an applier for multiple elastic rings for ligating fallopian tubes, stating that "[i]t is possible to load suture ring clips within the applicator in end-to-end series fashion. . . . This permits a number of clips to be applied during a procedure without the need of having to withdraw the applicator from the surgical field in order to load another clip into the applicator." U.S. Patent No. 4,226,239 to Polk also showed an instrument for endoscopic application of multiple ligating rings. The prior art also included at least one endoscopic multiple staple applier, Patent No. 4,944,443 to Oddsen. All of the endoscopic instruments for applying multiple fasteners had the common characteristics of elongation for use through a trocar, and most were sealed against escape of the gas through the trocar. Several references showed the use of silicon grease, as specified in claim 2 of the '057 patent, or valves, as specified in claim 1 of the '420 patent, to maintain the seal.

The testimony of U.S. Surgical's technical expert that the elongated body and the seal are common characteristics of endoscopic instruments was described by Ethicon as a concession of great weight. This evidence was stressed at trial, as Ethicon pressed its argument that U.S. Surgical had simply adapted its '226 patent multiple clip applier for endoscopic use, and that it was obvious to do so, pointing to many other instruments that had been adapted in the same way. U.S. Surgical points out that this same expert and several other expert witnesses testified about the difficulties of designing the '420/'057 endoscopic multiple clip applier and the time and cost involved. We take note of the conflicting testimony and the opposing expert opinions of witnesses for these parties, and of the lengthy explorations by these witnesses of this technology and the development and characteristics of these surgical instruments.

In comparing the '420/'057 instruments with the prior art instruments, Ethicon's patent expert testified that the prior art '226 patent was the closest prior art and that the relevant elements of the structure of the '226 patent "were adopted into the subject matter of the '057 and '420 patent applications."

Ethicon's technical expert pointed out to the jury all of the similarities of the structure and mechanisms between the device of the '226 patent and the '420/'057 patents. He pointed to the jaws to hold the clip, the pusher for advancing a stored clip to the jaws, the grooves in the face of the jaws to receive the clip, and the mechanism for closing the clip about the tissue to be ligated. The drawings of the jaws in the '226 patent and in the '420/'057 patents show this similarity:

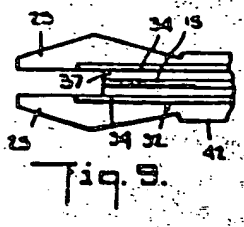

Fig 9 of 226 Patent

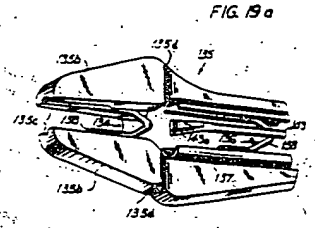

Fig 19a of 420 Patent

Witnesses testified that the operation of the '226 instrument and the '420/'057 patents was essentially the same. It was explained that in both the '226 and the '420/'057 instruments the jaw blade, clip carrier, and pusher bar are all enclosed in a channel assembly from which the jaws protrude at the end. In the '226 patent the applicator is described in the Abstract as:

> The surgical clip applicator has a pusher bar which positions the foremost clip from a clip carrier into a ready-to-fire position between the jaws prior to squeezing of the handles together. When the applicator is fired, the previously positioned surgical clip can be crimped about a vessel and when the jaws are released, a new clip is placed between the jaws for the next firing. A channel assembly moves over the jaws to close the jaws while the pusher bar is retracted into the clip carrier for delivering the foremost clip from the carrier upon release of the handles.

Referring to Fig. 4 of the '226 patent, it was explained at trial that the pusher bar (35) moves a clip (33) into the channels in the faces of the jaws (25). When a clip is in the jaws and the handles are closed, the external channel (38) moves forward over the beveled portion of the jaws, which, by virtue of their beveled shape, are squeezed together by the external channel, thus closing the clip. At the same time, the pusher bar moves back to engage the next clip in line. When the handle is released the channel withdraws, the jaws open and release the clipped tissue, and the pusher bar moves forward, positioning the next clip into the jaws. The operating components are shown in the patent as follows:

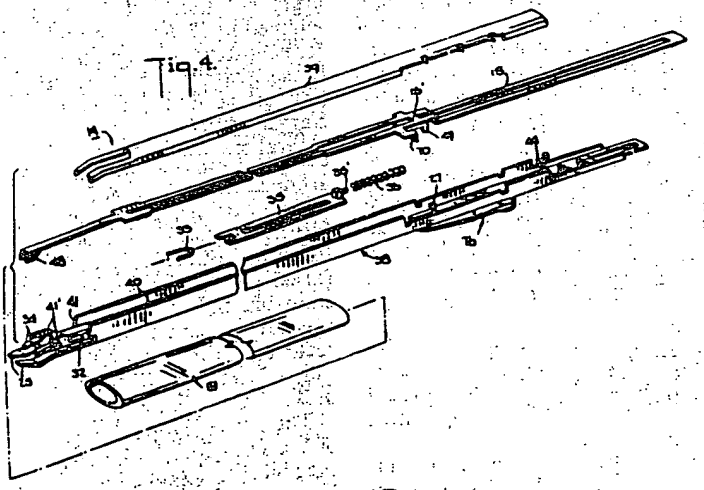

Fig 4 of 226 Patent

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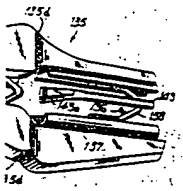
FIG. 19a



20 Patent

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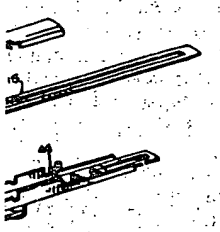

In the '226 patent the clip carrier is described as "an elongated channel having a pair of side walls or rails between which the clips are slidably guided, a pusher which slides between the rails, and a spring for biasing the pusher in the forward direction." Col. 4, lines 45-54. The corresponding assembly, shown in Fig. 18 of the '420 patent, was the subject of comparative testimony:

FIG. 18

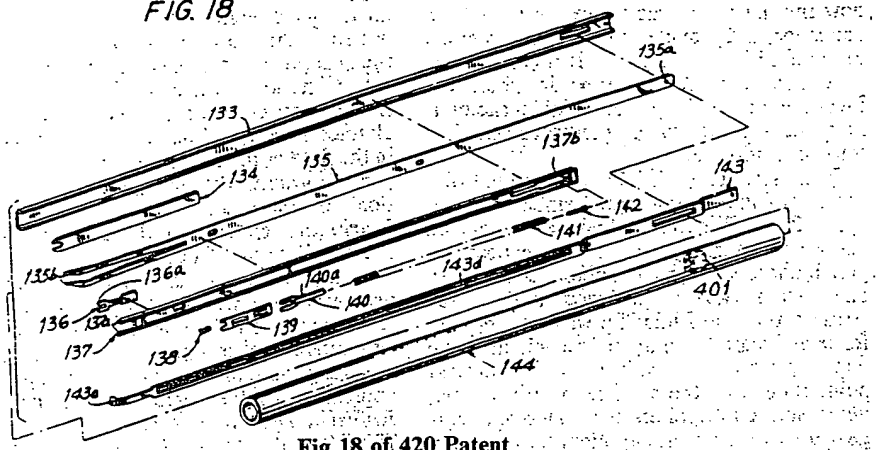

Fig 18 of 420 Patent

It was explained that the pusher bar (143) moves a ligating clip (138) into the channels in the faces of the jaws (135-b). When a clip is in the jaws and the handles are closed, the external channel (133) moves forward over the beveled portion of the jaws, squeezing them together and closing the clip.

To counter this evidence of similarity, U.S. Surgical witnesses testified that the '420/'057 instrument was not a routine adaptation of a prior instrument, and stressed the long development time and engineering difficulties involved in the conversion of the '226 device to endoscopic use. Ethicon challenged these arguments and their factual basis on cross-examination, and elicited testimony that the development time related primarily to unclaimed features of the handle.

There was testimony about the seal and how it was achieved. In its infringement case U.S. Surgical argued that "valve means" in the '420 patent included any known means for sealing the clip applier in the trocar, including valves and gaskets. U.S. Surgical argued at trial as stated in its proposed jury instruction construing this term for infringement purposes:

> The structure for performing this [valve means] function includes all such structures contained in trocars known in the art at the time the '420 Patent Application was filed.

U.S. Surgical presented testimony to this effect at trial, thus providing substantial basis for the jury to find that the "valve means" of the '420 patent was known in the prior art. U.S. Surgical does not now dispute that the "valve means" of its '420 patent is found in prior art endoscopic instruments.

In the course of the extensive explanation and comparisons at trial of the prior art devices and the '420/'057 devices, there was no dispute concerning the content of the references or the structures that they described. There was no dispute concerning the structures described in the '420/'057 patents, or concerning the meaning of technical terms or words of art as used in the prior art or in the patents in suit. The jury was instructed that the technical terms had their plain meaning, as the district court mentioned in its opinion on the post-trial motions. U.S. Surgical did not proffer a particular "construction" of technical terms in order to distinguish the claimed inventions from prior art devices. Neither party departed from the plain meaning of the words that were used in the claims and in the specifications, and in the prior art. Although U.S. Surgical has raised on this appeal the issue of "claim construction," as we shall discuss *post*, there was no argument at trial as to the meaning of technical terms or words of art insofar as they concern the determination of obviousness.

There was opinion evidence on both sides of the question of obviousness. We turn to the objective factors, for as the district court instructed the jury, such evidence must be

considered in the determination of obviousness:

Objective Factors

Objective factors assist in understanding how the invention was viewed in its field of endeavor, and provide an important practical guide to the decisionmaker. It was explained to the jury that the context in which the invention arose and its reception in the marketplace are indicia of unobviousness, and must be considered.

Witnesses for U.S. Surgical testified that the EndoClip, a commercial embodiment of the '420/'057 patents, had revolutionized endoscopic surgery and made endoscopic gall bladder removal possible. Its commercial success was emphasized, and it was stressed that the EndoClip was the first and for some years the only endoscopic multiple clip applier on the market. U.S. Surgical pointed out that the most relevant prior art, *viz.* single clip appliers for endoscopic surgery and multiple clip appliers for open surgery, had existed for more than a decade before U.S. Surgical produced the EndoClip for endoscopic surgery. U.S. Surgical presented evidence of the rapid acceptance and adoption of new endoscopic procedures, based on its new multiple-clip applier.

Witnesses for Ethicon testified that the growth of endoscopic surgery was due to the miniature video camera, not the multiple clip applier. They testified that before a tiny camera was available to televise images of the abdominal cavity, whereby a team of surgeons could operate with a common view of the surgical field, endoscopic surgery was largely limited to ligation of fallopian tubes, a simple procedure performed by a surgeon peering through an eyepiece. According to Ethicon, U.S. Surgical's EndoClip was developed for and had its only use for tubal ligation, and its later commercial growth was due to the sheer luck of being on the market when endoscopic surgery underwent its rapid expansion upon the capability of televising from inside the body.

Thus U.S. Surgical characterized its '420/'057 multiple clip applier as a pioneering advance in the field of endoscopic surgery, while Ethicon described the '420/'057 instrument as an obvious adaptation of a prior art multiple clip applier, whose commercial success was due to unrelated factors. These conflicting arguments were fully presented at trial. Witnesses, including surgeons, supported both sides. The jury was presented with questions of credibility and weight as well as factual disputes, as the jury decided whether the inventions of the claims in suit would have been obvious to a person of ordinary skill in the field of the invention at the time the invention was made. Although there were indeed questions of credibility and weight of evidence, the jury was not required to choose between alternative meanings of technical terms or words of art, or decide the scope of the claims, in deciding the question of obviousness. The factual findings of the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the field of the invention, and the objective considerations, did not require "construction" of these claims as set forth in the *Markman* decisions of the Federal Circuit and the Supreme Court.

In reviewing the jury verdict of obviousness, we review whether the jury was correctly instructed on the law, and whether there was substantial evidence whereby a reasonable jury could have reached its verdict upon application of the correct law to the facts, *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512, 220 USPQ 929, 935-36 (Fed. Cir.), *cert. denied*, 469 U.S. 871 (1984), recognizing that invalidity must be proved by clear and convincing evidence. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir. 1984). Thus we turn to the law, as presented at trial and as instructed by the trial judge.

The Jury Instructions

Jury instructions are reviewed for correctness, with due attention to their clarity, objectivity, and adequacy, taken as a whole. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1570, 24 USPQ2d 1401, 1411 (Fed. Cir. 1992) ("The correctness of a jury instruction . . . is reviewed on appeal to determine whether, on the whole, the jury instructions were adequate to ensure that the jury fully understood the legal issues for each element of the case."); *Trademark Research Corp. v. Maxwell Online, Inc.*, 995 F.2d 326, 339 (2d Cir. 1993) ("A trial court's improper charge constitutes reversible error only 'when jury instructions, taken as a whole, give the jury a misleading impression or inadequate understanding of the law.'") (quoting *Carvel Corp. v. Diversified Management Group, Inc.*, 930 F.2d 228, 232 (2d Cir. 1991)).

[1] The jury was correctly instructed on the presumption of validity, and that Ethicon bore the burden of proving invalidity by clear and convincing evidence. The jury was correctly instructed that in determining whether the inventions of the '420 and '057 patents

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were invalid based on obviousness, it was necessary to consider the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and the objective criteria of unobviousness. The court correctly explained the *Graham* factors. *See Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). For example, in determining the level of ordinary skill in the art the jury was instructed to consider

> evidence submitted by the parties to show:
>
> One, the educational level of active workers in the field;
>
> Two, the types of problems encountered in the art;
>
> Three, the nature of the prior art solutions to those problems;
>
> Four, the activities of others;
>
> Five, the rapidity with which innovations are made in the art;
>
> And six, the sophistication of the technology involved.

The jury instructions included explanation of the principles to be applied in determining obviousness when the invention is a combination of prior art components. The court instructed that the prior art must show not only all of the elements of the claimed combination, but must contain some "teaching, suggestion or incentive" to a person of ordinary skill to combine the known elements in the way that U.S. Surgical combined them:

> In order to prove obviousness, the defendants must prove, again by clear and convincing evidence, that one of ordinary skill in the art would have found in the prior art references some teaching, suggestion or incentive to combine the prior art references in the way that U.S. Surgical did in its invention.

The jury instructions stressed that the prior art, to be invalidating, must sufficiently teach or direct a person of ordinary skill how to obtain the result reached by the patentee:

> Additionally, if you do find a teaching in the prior art that would motivate one of ordinary skill in the prior art to make the clip applier claimed in the '057 and '420 patents, you must also determine whether there was sufficient teaching or direction in the prior art of how to obtain or build the claimed clip applier such that a person of ordinary skill in the art would have a reasonable likelihood of success in making the invention. In other words, in order to find obviousness, you must find not only that the prior art would teach one of ordinary skill to try the combination of known elements, but also that the prior art would sufficiently teach or direct one of ordinary skill how to obtain the desired result.

The jury was instructed that in determining obviousness it was to consider the claim as a whole, and that it did not suffice if the individual elements of the invention were known in the prior art:

> The reason you must consider the claim as a whole is because there is no dispute that U.S. Surgical's invention is comprised of individual elements which were known in the prior art. The fact that U.S. Surgical's inventions incorporate or combine elements already known in the prior art does not render its patents invalid. Patents can be granted on devices that contain a combination of various elements that are well known in the prior art. U.S. Surgical's claim is that it invented the combination of those elements for the first time in the endoscopic multiple clip applier claimed in the patents in suit.

The instructions on the law of obviousness occupied eight pages of trial transcript. They were correct in law, thorough, and clearly stated. U.S. Surgical now argues that other instructions that it requested should also have been given, and that their omission requires a new trial. The district court explained its denial of these requests in its opinion on the post-trial motions.

U.S. Surgical had requested that the court read to the jury the sentence of 35 U.S.C. §103(a) that states: "Patentability shall not be negatived by the manner in which the invention was made," accompanied by the instruction that the jury should give no weight to Ethicon's evidence of "how long or short a time it took to make [the invention]" and "how obvious U.S. Surgical's invention may have seemed to U.S. Surgical's own inventors." The court denied the request. We do not discern reversible error in this denial, for the rejected instruction was encompassed in the instructions that were given, was the subject of expert testimony, and was included in the argument. The court did not commit error in denying an instruction that gave weight to one of the several aspects that were before the jury, and was reasonably viewed as cumulative in the context of the instructions that were given.

U.S. Surgical also requested an instruction that the '226 patent was cumulative prior art and thus did not have to be cited to the patent examiner. In its pre-trial consideration of the issue of inequitable conduct the court, through a special master, had concluded that the '226 patent was cumulative in the circumstances and on the law that then applied in the examination of patents. Whatever the relevance of this point to the issue of

inequitable conduct, which had been decided in favor of U.S. Surgical, the '226 patent was correctly treated as prior art in this litigation. The denial of this instruction is not grounds for a new trial.

U.S. Surgical also requested the instruction that even if the jury found the absence of the secondary consideration of long-felt need, that was "in no way suggestive of obviousness or invalidity." The instruction that was given on the secondary considerations was:

> In making these three determinations [the *Graham* factors] you must also consider other surrounding circumstances which are called secondary considerations. These include:
>
> One, whether the alleged invention was commercially successful;
>
> Two, whether the alleged invention satisfied a long-felt need in the art;
>
> Three, whether others were unsuccessful in making the alleged invention;
>
> Four, whether the alleged invention was copied by others in the art;
>
> Five, whether the alleged invention received praise from others in the art;
>
> Six, whether the alleged invention departed from other principles of the art.
>
> In order to determine that secondary considerations such as commercial success are evidence of non-obviousness, there must be a causal connection between the patented features of the invention and the commercial success of the device. If commercial success is attributable to the patented features, then it is evidence of non-obviousness.

U.S. Surgical's requested instruction concerning long-felt need related to the weight to be given to a fact whose existence, and significance, was disputed at trial. The issue of the objective factors was complex and hard-fought at trial, leaving areas of dispute, weight, and perhaps credibility. We discern no error in the court's refusal to comment on a specific aspect, having instructed the jury on all aspects.

U.S. Surgical also requested the instruction that prior art that teaches away from the patented invention is evidence of nonobviousness. That subject was comprehended in the above-quoted instruction that the jury should consider "Six, whether the alleged invention departed from other principles of the art," an argument whose substance had been debated at trial. The refusal of this instruction, in light of the full instructions that were given, is not grounds for a new trial.

U.S. Surgical also states that the district court should have given a curative instruction to counter Ethicon's suggestion that the patents in suit improperly hindered competition. The record shows Ethicon's persistent and improper innuendos. However, U.S. Surgical reasonably countered this aspect with evidence and argument concerning the purpose of the patent system. Review of the record leads us to conclude, as apparently did the district court, that this tactic did not prejudice the outcome. *See City of New York v. Pullman, Inc.*, 662 F.2d 910, 917 (2d Cir. 1981) ("The district court is not obliged to charge every contention made by the parties at trial, as long as the charge itself, taken as a whole, is fundamentally fair.") (citations omitted), *cert. denied*, 454 U.S. 1164 (1982). The denial of these instructions (and others offered by both sides) was not a miscarriage of justice, and does not establish reversible error or grounds for a new trial.

U.S. Surgical also argued that its requested instructions construing the claims should have been given, and that the absence of "claim construction" by the district court required a new trial. In accordance with the Court's remand for further consideration in light of *Markman*, we have again reviewed the requested instructions to determine whether any instructions that were improperly refused could reasonably have prejudiced the jury's verdict of invalidity.

In evaluating the refused instructions, we look first at the instructions on claim construction that were given. The issue was interpretation of these means-plus-function claims and their application to find if there was infringement by the Ethicon devices. The district court instructed the jury how to interpret means-plus-function claim elements, and how to apply these claim elements to the accused devices, as follows:

> Now, in interpreting the means plus function claim elements, you must determine the following:
>
> One, what function is called for by the claim element, and
>
> Two, what structure, or means, is described in the patent specifications for performing the stated function.
>
> A means plus function claim is only infringed if:
>
> One, the function of the accused device is identical to the function disclosed in the claim element of the patent; and
>
> Two, the structure which performs that function in the accused device is the same as, or the equivalent of, the structure described in the patent specifications.
>
> The second of these two steps requires you to determine whether the accused device includes the same structure as described in the patent or its equivalent. You

n's suggestion that the erly hindered competi- vs Ethicon's persistent ndos. However, U.S. countered this aspect gument concerning the system. Review of the nclude, as apparently that this tactic did not ie: *See City of New* , 662 F.2d 910, 917 (2d ict court is not obliged ntion made by the par- the charge itself, taken mentally fair.") (cita- *lenied*, 454 U.S. 1164 these instructions (and sides) was not a mis- nd does not establish unds for a new trial. rgued that its request- uing the claims should l that the absence of by the district court n accordance with the rther consideration in e have again reviewed ictions to determine ons that were improp- asonably have preju- t of invalidity. fused instructions, we uctions on claim con- given. The issue was e means-plus-function ication to find if there the Ethicon devices. ructed the jury how to -function claim ele- pply these claim ele- devices, as follows: eting the means plus nents, you must deter- on is called for by the ure, or means, is de- ent specifications for ed function. nction claim is only of the accused device nction disclosed in the e patent; and e which performs that sed device is the same t of, the structure de- t specifications. ese two steps requires ether the accused de- ame structure as de- or its equivalent. You

> may determine that a structure in the Ethicon device is equivalent if you determine that a person of ordinary skill in the art would consider the structure found in the accused device an insubstantial change from the structure disclosed in the patent specification.

This aspect did not concern, or determine, validity in this case. However, U.S. Surgical states that *Markman* requires the trial judge to perform the first portion of this instruction, that is, to determine the function and the structure or means that performs the function, and to give a detailed technical analysis for the infringement portion of the instruction; and that failure to do so fatally flawed the trial.

For example, U.S. Surgical requested instructions for the first element of claim 1 of the '057 patent, starting with the following proposed claim construction:

> Clause i) of claim element 1b) reads "means for storing a plurality of surgical clips." This is a means-plus-function claim element. The stated function, as I interpret it, is to store a plurality of surgical clips.

We observe that this part of the proposed claim construction merely repeats the words of the claim. The requested instruction then told the jury what structure was described in the patent specification for performing this function:

> The structure or means disclosed in the patent specification for performing this function is a clip track which holds an array of surgical clips and a spring to bias the clips toward the distal or far end of the instrument.

This information from the specification resolved no dispute, for there was none. Next, the requested instruction told the jury how to find infringement: the same instruction as in the general jury instruction that was actually given, quoted *supra*, but now drawn specifically to this claim element:

> In order to find that this claim element of the '057 patent has been met, you must first find that defendants' accused devices perform the function of storing a plurality of clips. Then you must find that the defendants' accused devices have a clip track which holds an array of surgical clips and a spring to bias the clips toward the distal or far end of the instrument, or equivalent structure, which performs this function.

This text, again, repeated the function in the same words as in the claim, and repeated the undisputed description in the specification. The requested instruction then stated that if the accused devices perform this function, using the described means or an equivalent means, there is infringement. That is the same instruction as in the general instruction that was actually given, but made specific to this claim element. We doubt that *Markman* requires the trial judge to instruct as to an undisputed "claim construction" for every term, by simply parroting the words of the claim and then repeating the rule concerning infringement of means-plus-function claims. *Markman* explicitly recognized that the application of the claim to the accused device was for the jury. Indeed, Ethicon objected to this instruction as an improper attempt to direct the jury findings of infringement.

Similar instructions were proffered for the other claim elements. Another rejected instruction started with a similar repetition of the words of the claim as "interpreted" by the judge, and an undisputed restatement of what these words mean:

> The final clause of claim element b) ii) calls for "clip closing means for sequentially closing said surgical clips." This is a means-plus-function claim element. The stated function of this particular means-plus-function claim element is "sequentially closing said surgical clips." I interpret this to mean the closing of surgical clips one at a time and one after the other.

In the infringement trial, the issue was not the definition of "sequentially," but the equivalency of the means that was described in the specification with the means that was used in the accused device, and issues concerning the clip advancing means. These aspects do not relate to obviousness, but to infringement. The additional text of this proposed instruction was objected to on its merits by Ethicon as an incorrect application of the law of 35 U.S.C. §112 ¶6. However, this aspect raised no disputed issues with respect to the determination of obviousness in view of the prior art. The dispute concerning the requested instructions related not to the prior art, but to the accused Ethicon devices.

Following is another claim element whose proffered "interpretation" was to repeat the words of the claim:

> Claim element a) calls for a trocar having a cannula with valve means for sealing the cannula. The claim element "valve means for sealing said cannula" is a means-plus-function claim element. The stated function, as I interpret it, is to seal the cannula.

There were infringement disputes concerning the valve means, and there was much debate at trial concerning the scope of this claim element as applied to Ethicon's devices. U.S. Surgical requested the instruction that the "valve means" includes and is infringed by all prior art valves and gaskets

and any other known structures for sealing the cannula:

> The structure for performing this function includes all such structures contained in trocars known in the art at the time the '420 Patent Application was filed. Such trocars contain structures both to seal the cannula when no instrument is in the cannula, such as a flapper-type valve, and structures which form a seal between the instrument and the cannula when an instrument is inserted in the cannula, such as a gasket. The flapper valve may engage the gasket, as in the U.S. Surgical Surgiport Trocar, or be separate from the gasket, as in reusable instruments that were known at the time the '420 Patent Application was filed. Therefore, if you find that the Ethicon Endopath Trocar is a trocar having the same or equivalent structure to the structures I have just described, then the accused devices satisfy claim element a) of Claim 1 of the '420 Patent.

We referred *supra* to this requested instruction, for it makes clear that validity of the U.S. Surgical patents was not grounded on asserted unobviousness of the valve means, and that a reasonable jury could have so found. The district court had left to the jury the issue of breadth of the valve means as it affected infringement, for Ethicon had vigorously objected to this instruction as prejudging the finding of infringement. In his post-trial opinion, the district judge expressed the view that the jury had accepted U.S. Surgical's construction of the valve means since it found infringement of the '420 patent claim. We do not reach the issue of infringement. However, whether the valve means was construed as broadly as U.S. Surgical requested, or quite narrowly as Ethicon had argued, the variety of valve structures shown in the prior art was in accordance with the jury's finding of obviousness in light of the prior art.

[2] The *Markman* decisions do not hold that the trial judge must repeat or restate every claim term in order to comply with the ruling that claim construction is for the court. Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy. Although claim construction may occasionally be necessary in obviousness determinations, when the meaning or scope of technical terms and words of art is unclear and in dispute and requires resolution in order to determine obviousness, in this case none of these rejected instructions was directed to, or has been shown reasonably to affect, the determination of obviousness.

Grounds for a new trial have not been shown. *See Santa Maria v. Metro-North Commuter R.R.*, 81 F.3d 265, 273 (2d Cir. 1996) ("A new trial must be granted if the court determines that 'the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair to the party moving.' ") (quoting *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940)); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 626, 225 USPQ 634, 643 (Fed. Cir. 1985) ("If prejudicial error occurred, or if the verdict is against the clear weight of the evidence, as an alternative to judgment n.o.v. a new trial may be granted, in the discretion of the trial judge.").(citing *Fairmont Glass Works v. Cub Fork Coal Co.*, 287 U.S. 474 (1933)).

We have not been shown prejudicial error in the jury instructions, or that the verdict of obviousness is against the clear weight of the evidence, or that substantial justice requires that the trial be voided.

The Dictionary

During its deliberations the jury requested a dictionary and, over the objections of both parties, was provided one by the court. U.S. Surgical states this is reversible error, while Ethicon states that any error was harmless.

U.S. Surgical proposes that the jury might have used the dictionary to look up definitions on which it had been instructed by the court or that had been explained by witnesses, such as "presumption" or "obviousness." The jury was instructed, as the parties agreed, to consider the ordinary meaning of the language used in the claims. U.S. Surgical does not mention any terms that were used outside of their ordinary meaning. The district court pointed out in its post-trial opinion that the instruction to consider the ordinary meaning, and the general assumption that definitions in a standard dictionary are common knowledge with which the jury is charged, support the provision of the dictionary.

[3] It is generally agreed that the provision of a dictionary to a jury, although not favored, is not grounds for a new trial. *See Wernsing v. General Motors Corp.*, 470 A.2d 802, 806 (Md. 1984) ("It appears to be the near universal consensus that a new trial is not awarded simply because a dictionary was before the jury.") (citing cases). U.S. Surgical offered no specifics as to words whose dictionary definitions may have adversely affected the verdict of obviousness.

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Instead, U.S. Surgical seeks a presumption of prejudice and an automatic new trial.

Both sides cite *United States v. Weiss*, 752 F.2d 777 (2d Cir. 1985), as stating the controlling law in the Second Circuit, and each side argues that *Weiss* supports its position. In *Weiss* a criminal defendant was convicted of mail fraud, perjury, and RICO violations, and the jury obtained accounting books without the judge's knowledge or consent. Although the Second Circuit stated that "extra-record information that comes to the attention of a juror is presumptively prejudicial," 752 F.2d at 782-83, the court held that the trial judge's determination that the information had not prejudiced the defendant was not an abuse of discretion, and sustained the conviction.

U.S. Surgical argues that the practice of permitting the jury to have a dictionary would undermine the patentee's right to be its own lexicographer, and thus constitutes reversible error. However, U.S. Surgical does not direct us to any actual or reasonably possible prejudice, or any suggestion that the jury disregarded the court's instructions on the law of obviousness, or the plain meaning of the terms used in the claims and the prior art. Instead, U.S. Surgical argues that it was Ethicon's burden to establish that the jury did not misuse the dictionary, and that since that burden can not be met a new trial is required. However, the holding in *Weiss* was not for an automatic new trial. *Weiss* did not divest the trial judge of authority to decide whether the error, in that case viewed as juror misconduct, was in fact prejudicial.

The district court did not commit prejudicial error by providing the dictionary. A new trial on this ground is not warranted.

The Post-Trial Motions

Upon post-trial motions the district court, in a 34-page opinion, discussed validity and infringement. With respect to validity the court discussed the positions of the parties on the teachings of the prior art, the differences between the prior art and the patented inventions, and how the inventions as a whole would have been viewed by a person of ordinary skill in that art.

The district court summarized the evidence that the prior art would have suggested the combination claimed in the '420 patent. The court referred to Ethicon's position that U.S. Surgical had adapted its own multiple clip applier to endoscopic use, and the testimony that the only significant difference from the prior art multiple clip applier was the elongation of the shaft and the seal, and that these were common to all endoscopic instruments.

The district court explained its conclusion that there was substantial evidence in support of the jury verdict of obviousness of the claims in suit. The court also explained its conclusion that the requirements of a new trial had not been met: that the verdict was not against the weight of evidence, that there was not a miscarriage of justice or prejudicial error during trial, or a seriously erroneous result.

The Motion Upon Remand

Following the remand from the Supreme Court to the Federal Circuit, U.S. Surgical moved this court to vacate the district court's judgment and order a new trial, on the ground that since the district court had not construed the claims as required by *Markman*, either before or after the jury rendered its verdicts, there is nothing for the Federal Circuit to review on appeal. U.S. Surgical states that it is entitled to a new trial of all issues of validity and infringement except for the verdicts in its favor (infringement of the '420 patent and that there was not inequitable conduct) for which Ethicon did not petition for *certiorari*.

Ethicon, opposing the motion, points out that the district court, in its opinion on the post-trial motions, discussed the claim construction that the jury necessarily adopted on the two aspects of claim scope that were in genuine dispute as applied to the Ethicon devices. Ethicon points out that the district court stated that it agreed with the jury's necessary constructions with respect to the valve means and the clip advancing means, and that the court explained its reasons for sustaining the verdicts based on those constructions. Ethicon points out that under *Markman* this court undertakes to perform any necessary claim construction *de novo*. Ethicon also points out that no disputed claim construction was material to the determination of obviousness.

[4] Concerning U.S. Surgical's proposed instructions on claim construction, as we have discussed, whatever their applicability to the issues of infringement, their omission did not prejudice the issue of obviousness. *Markman* did not hold that the trial judge must always parse the claims for the jury, whether or not there is an issue in material dispute as to the meaning or scope of the claims. Neither this court nor the Supreme Court held that the trial judge must conduct such a rote exercise, on pain of having to retry the case.

Ethicon had objected to the substance of U.S. Surgical's proposed instructions, as well as asserting that they were unnecessary. We need not resolve this issue, for U.S. Surgical

has not shown that there are unclear or ambiguous technical terms or words of art or related aspects of claim scope whose "construction" as requested by U.S. Surgical would negate the verdicts of obviousness. The jury was instructed, without objection, that the language of the claims was to have its plain meaning. There was no dispute as to the meaning of technical terms or words of art as used in either the prior art or the claims. The difference between the prior art and the claimed invention is a question of fact, *Graham*, 383 U.S. at 17, 148 USPQ at 467, and was not overruled by the Court's *Markman* decision.

U.S. Surgical argues that if the district court had construed the claims for the jury, the jury could not have reasonably accepted Ethicon's argument that U.S. Surgical had simply made known endoscopic adjustments in its prior art multiple clip applier. This went to the ultimate question of obviousness, which was decided by the jury upon finding and weighing and evaluating the factual evidence of the *Graham* factors. U.S. Surgical does not explain how any reasonable claim construction that it requested would have deprived the verdict of obviousness of its support. Further, *Markman* does not authorize the trial judge to remove from the jury the factual findings required by *Graham*.

On careful consideration of the substance of the instructions on claim construction that the district court declined to give, and the instructions on the issue of obviousness, all in light of the particular issues in this case concerning the prior art, the claimed invention, and the Court's discussion in *Markman*, we conclude that the omission of the requested instructions did not prejudice the determination of obviousness. The criteria for grant of a new trial have not been met. *See Santa Maria*, 81 F.3d at 273; *Shatterproof Glass*, 758 F.2d at 626, 225 USPQ at 643 (new trial appropriate when there was prejudicial error, or when verdict against weight of the evidence).

Conclusion

On review of the proceedings at trial, we conclude that there was substantial evidence from which a reasonable jury could have held that the claimed subject matter would have been obvious to a person of ordinary skill in this field at the time the invention was made. The judgment of invalidity is affirmed.

The case was vigorously litigated, with extensive testimony, physical exhibits, and argument. We have been directed to no unfairness or incompleteness or prejudice in the jury instructions with respect to obviousness. A new trial was properly denied.

Costs

Costs to Ethicon.

AFFIRMED; MOTION FOR NEW TRIAL DENIED.

U.S. Court of Appeals
Federal Circuit

Micro Chemical Inc. v. Great Plains Chemical Co.

Nos. 95-1504, -1514

Decided January 3, 1997

PATENTS

1. Patentability/Validity — Anticipation — Prior sale — Degree of development (§115.0707.05)

Federal district court erred in holding patent directed to method and apparatus for adding small amounts of ingredients to livestock or poultry feed invalid under on-sale bar of 35 USC 102 based on inventor's offer, before critical date, to sell weighing machine to feedlot manager, since at time of alleged offer, inventor had not reduced invention of patent to practice, had not substantially completed invention, and had not demonstrated high likelihood that invention would work for its intended purpose, and since inventor's "offer" therefore could not trigger on-sale bar.

2. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Patentability/Validity — Obviousness — Combining references (§115.0905)

Patent directed to method and apparatus for adding small amounts of ingredients to livestock or poultry feed would not have been obvious in view of prior art weighing machine and prior art volume machines in combination, since there is no evidence of motivation or suggestion to combine prior art machines, since motion of mixing elements in volume machine would have been expected to cause inaccurate weighing, and prior art therefore led away from idea of combining features of weighing and volume machines, and since inventor's extensive efforts to solve problem of isolating weighing system tend to show that one skilled in art would